

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Charles S. Taylor et al.

Serial No.: 09/480,828

Filed: January 10, 2000

For: ACCESS PLATFORM FOR
INTERNAL MAMMARY
DISSECTION

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

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TRANSMITTAL LETTER FOR REQUEST FOR DECLARATION OF INTERFERENCE
UNDER 35 U.S.C. § 135 AND 37 C.F.R. § 1.607

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The following documents are enclosed for filing.

(1) Request for Declaration of Interference Under 35 U.S.C. § 135 and 37 C.F.R. § 1.607,
which includes:

- (a) Appendix A - Claim Support in Application No. 09/480,828;
- (b) Appendix B - Claim Support in Application No. 08/619,903;
- (c) Appendix C - Claim Support in Application No. 08/604,161;

OC-43407.1

CERTIFICATE OF MAILING
(37 C.F.R. § 1.8a)

I hereby certify that I have a reasonable basis to expect that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

January 24, 2000
Date of Deposit

Alexis L. Kovacs

- (d) Exhibit 1 - U.S. Patent No. 5,882,299 (Rastegar et al.);
 - (e) Exhibit 2 - Specification of Application No. 08/619,903;
 - (f) Exhibit 3 - Specification of Application No. 08/604,161;
- (2) Preliminary Amendment and Notification of Copied Claims for Proposed Interference;
- (3) Receipt verification postcard.

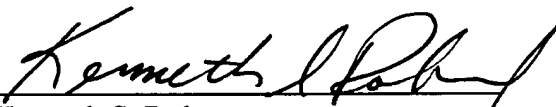
The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 12-2475. (Customer Code Number: 22249).

Respectfully submitted,

LYON & LYON LLP
Attorneys for Applicants

Dated: January 24, 2000

By:


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Patent

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REQUEST FOR DECLARATION OF INTERFERENCE
UNDER 35 U.S.C. § 135 AND 37 C.F.R. § 1.607

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

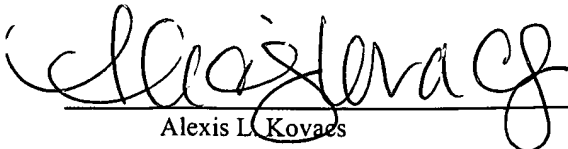
In accordance with 35 U.S.C. §135 and 37 C.F.R. §1.607, applicants respectfully request the declaration of an interference between the instant application and U.S. Pat. No 5,882,299 to Hassan Rastegar et al., attached hereto as Exhibit 1, having the proposed Counts set forth herein.

OC-43093.1

CERTIFICATE OF MAILING
(37 C.F.R. §1.8a)

I hereby certify that I have a reasonable basis to expect that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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Alexis L. Kovacs

REMARKS

U.S. Patent No. 5,882,999 (Exhibit 1) issued on March 16, 1999 to Hassan Rastegar et al. (hereinafter "the Rastegar patent"). The present application is a continuation of co-pending application Serial No. 09/385,812, filed August 30, 1999, which in turn is a continuation of Serial No. 08/903,516, filed on July 30, 1997, now issued as U. S. Patent No. 5,944,736, which in turn is a continuation of Serial No. 08/787,748, filed on January 27, 1997, now abandoned, which in turn is a continuation-in-part of application Serial No. 08/619,903, filed on March 20, 1996, now issued as U.S. Patent No. 5,976,171, which in turn is a continuation-in-part of co-pending application Serial No. 08/604,161, filed on February 20, 1996, now issued as U.S. Patent No. 5,730,757. The present application claims the benefit under 35 U.S.C. §120 of these previously filed United States patent applications.

Please be advised that the claims included in the above-identified application, and presented in this Request for Interference, are introduced for the purpose of provoking an interference with the Rastegar patent. Applicants' claims 1, 2, 3, 4, 5, 6, and 7 were copied verbatim from the Rastegar patent and are identical to claims 1, 2, 7, 8, 9, 10, and 11, respectively, of the Rastegar patent. Applicants' claims 8-18 were substantially copied from the Rastegar patent, with only minor differences in claim language, and correspond to claims 1-11, respectively, of the Rastegar patent. Because Applicant's effective filing date is January 27, 1997, Applicant is senior to the filing date of January 31, 1997 for the Rastegar patent. Thus, Applicant need not present a prima facie showing pursuant to 37 C.F.R. § 1.608. However, in addition to showing support for the copied claims in the instant application, which appears in Appendix A to this Request for Interference, Applicants are able to show support for the copied claims in related application nos. 08/619,903 (filed March 20, 1996) and 08/604,161 (filed February 20, 1996), which are attached hereto as Exhibits 2 and 3,

respectively. The support for copied claims found in application nos. 08/619,903 and 08/604,161 appears in Appendix B and C, respectively, to this Request for Interference.

In accordance with 37 CFR § 1.607, the copied claims may be specifically applied to Applicants' disclosures in the instant application and related application nos. 08/619,903 and 08/604,161 as set forth in Appendices A, B, and C, respectively. Although the cited specification support appearing in Appendices A, B, and C is extensive, the cited support is not intended to be exhaustive. Applicants, therefore, reserve their right to establish support by reference to specification text and figures not cited herein.

Before addressing the counts for this Request for Interference, both the Rastegar patent and the instant application will be generally discussed.

The present application discloses an apparatus and associated methods for providing improved access to a patient's internal mammary artery (IMA) to enable the surgeon to dissect the IMA and to perform the necessary arteriotomy and anastomosis procedures which are part of a surgical procedure known as the Coronary Artery Bypass Graft (CABG) procedure. The present application discloses a CABG procedure performed on a patient's beating heart. In the preferred method, a heart stabilizer is used to reduce movement of the patient's heart. In general, the disclosed apparatus, referred to as an access platform, is inserted between a patient's ribs and then used to separate and vertically offset the patient's ribs to access the patient's IMA. The access platform can be used to mount additional instruments needed to perform the CABG procedure, such as a heart stabilizer used to reduce movement of the heart. The access platform generally includes a spreader member, first and second blade arm members connected to the spreader member, first and second blades attached to first and second blade arms, and an offset member connected to one of the blades and the spreader member. The blades and blade arms may be pivotally connected to the spreader member. In operation, the blades are inserted in an incision into the patient's chest between adjacent

ribs. Once the blades are in place, the spreader member is actuated to laterally separate the blades while the offset member causes one of the blades to be vertically offset relative to the other blade to provide access to the IMA. With the blades separated and offset, the IMA is dissected. While movement of the heart is preferably reduced by a stabilizer apparatus, arteriotomy and anastomosis procedures are performed to connect the dissected IMA to an occluded coronary artery.

The Rastegar patent claims a device for insertion between and separation of juxtaposed ribs and for lifting of a portion of the patient's ribcage. According to claim 7 of the Rastegar patent, the device includes first and second arm members having proximal portions hingedly connected to distal portions, wherein the distal portion includes a rib engaging blade, a mechanism that operably connects the first and second arm members such that the arm members are movable toward and away from each other, and a lifting mechanism for lifting the blade of the second arm member and a portion of the patient's ribcage. The Rastegar patent also claims two (2) anastomosis procedures for a blocked coronary artery of a heart. In the first procedure recited in claim 1, an incision is first provided in an intercostal space between two ribs of the patient, a spreader device is then inserted between the two ribs to engage the first and second ribs, the spreader device is then lifted to lift the second and juxtaposed ribs to expose the IMA, the IMA is then dissected, and an anastomosis procedure is then performed using the dissected IMA. The second procedure recited in claim 4 is similar to claim 1. Contrary to claim 1, Claim 4 does not include a lifting step and requires the steps of pharmaceutically treating the heart to reduce its movement and clamping an occluded coronary artery at spaced apart positions at an anastomosis site.

PROPOSED COUNTS

Applicants propose three (3) separate Counts for this interference; the first and second counts being directed to separate method claims and the third count being directed to the apparatus claims. The Counts are set forth separately below. Please note that the Counts and Applicants' claims presented as corresponding to the Counts, are fully supported and are disclosed at least as early as January 27, 1997 and substantially supported and disclosed as early as February 20, 1996, the filing date of Application No. 08/604,161 (Exhibit 3). Accordingly, Applicants should be senior party with respect to the subject matter of the requested interference.

Further, as established by the specification support set forth in Appendix A, the copied claims do not add any new matter to the instant application. In addition, the specification of the instant application describes what was the best mode of practicing the invention known to the inventors at the time of filing, and that by corresponding various elements of the disclosed embodiments to any claim it is not to be inferred that Applicants' invention is limited to that disclosed embodiment.

COUNT I

Count I is set forth below:

- I. A minimally invasive coronary anastomosis procedure for a blocked coronary artery of a heart, the procedure comprising:

providing an incision in an intercostal space between two ribs of a patient, the incision providing access to a selected anastomosis site;

inserting into the incision a first blade to engage a first rib and a second blade to engage a second rib, and spreading apart the first and second blades to spread apart the first and second ribs;

lifting the second blade to offset the second blade and rib relative to the first blade and rib thereby exposing an internal mammary artery to direct visualization;

dissecting the internal mammary artery; and

performing the anastomosis.

COUNT II

Count II is set forth below:

II. A minimally invasive coronary anastomosis procedure for a blocked coronary artery of a heart, the procedure comprising:

providing an incision in an intercostal space between two juxtaposed ribs of a patient, the incision providing access to a selected anastomosis site on the blocked coronary artery;

inserting a spreader device between the two juxtaposed ribs such that when the spreader device is operated, the ribs are spread apart widening the incision;

dissecting an internal mammary artery;

reducing movement of the heart;

incising the blocked coronary artery downstream from the blockage; and

suturing the dissected internal mammary artery to the incision on the blocked coronary artery at the selected anastomosis site.

COUNT III

Count III is set forth below:

III. A device for use in a surgical procedure in which an incision is made between two juxtaposed ribs of a patient, the device comprising:

a first arm member having a proximal end portion and a distal end portion, the distal end portion having a rib engaging blade, and the distal and proximal end portions being hingedly attached to each other;

a second arm member having a proximal end portion and a distal end portion, the distal end portion having a rib engaging blade and the distal and proximal end portions being hingedly attached to each other;

a mechanism that operably connects the first and the second arm members at the proximal end such that the arm members are movable toward and away from each other; and

a rib offsetting device, the device being operably coupled to the blade of the second arm member, and adapted to move the blade portion of the second arm member in an upward direction thereby lifting the blade of the second arm member which results in lifting a section of the patient's ribs

Applicants submit that claims 1, 2, and 3 of the Rastegar patent (Exhibit 1) correspond to proposed Count I, that claims 4, 5, and 6 of the Rastegar patent correspond to proposed Count II, and that claims 7, 8, 9, 10, and 11 of the Rastegar patent correspond to proposed Count III. Applicants further submit that application claims, as presented below, correspond to the proposed counts as follows: claims 1-2 and 8-10 correspond to proposed Count I; claims 11-13 correspond to proposed Count II; and claims 3-7 and 14-18 correspond to proposed Count III. In conformance with 35

U.S.C. § 135(b), the presented claims were copied upon filing of the subject application on January 10, 2000, which is prior to one year from the date on which the Rastegar patent was granted.

Claims Presented for Interference

1. A minimally invasive coronary anastomosis procedure for a blocked coronary artery of a heart, the procedure comprising:

providing an incision in an intercostal space between two ribs of a patient, the incision providing access to a selected anastomosis site;

inserting a spreader device between the two ribs, the spreader device having a first end for engaging the first rib and a second end for engaging the second rib;

lifting the spreader device such that the second and juxtaposed ribs are elevated with respect to the first rib thereby exposing an internal mammary artery sufficiently for direct visualization;

dissecting the internal mammary artery; and

performing the anastomosis through the incision using the internal mammary artery.

2. The procedure of claim 1 wherein the patient is positioned on a surgical table, and wherein the spreader device is lifted using a lifting mechanism that is mounted to the surgical table and extends upwardly to a position above the patient.

3. A device for use in a surgical procedure in which an incision is made between two juxtaposed ribs of a patient, the device comprising:

a first arm member having a proximal end portion and a distal end portion, the distal end portion having a rib engaging blade, and the distal and proximal end portions being hingedly attached to each other;

a second arm member having a proximal end portion and a distal end portion, the distal end portion having a rib engaging blade and the distal and proximal end portions being hingedly attached to each other;

a mechanism that operably connects the first and the second arm members at the proximal end such that the arm members are movable toward and away from each other; and

a retractor lifting device, the device comprising a blade portion for engaging the blade of the second arm member, and a post member secured to an operating table on which the patient lies, and a handle section to which the blade section is movably attached, and a mechanism for moving the blade portion in an upward direction thereby lifting the blade of the second arm member which results in lifting a section of the patient's ribs.

4. The device of claim 3 wherein the mechanism includes a rack bar fixedly attached to the first arm member at one end and at another end movably engages the proximal end portion of the second arm member such that the second arm member moves away and toward the first arm member along the rack bar.

5. The device of claim 3 wherein the first arm member further includes two hinge sections and a mid-section that is hingedly attached to the proximal end portion at one end and to the distal end portion at another end.

6. The device of claim 3 wherein the second arm member further includes two hinge sections and a mid-section that is hingedly attached to the proximal end portion at one end and to the distal end portion at another end.

7. The device of claim 3 wherein the distal end portion of the first arm member further includes a plurality of fingers extending away from the blade for retaining fatty tissue away from the incision.

8. A minimally invasive coronary anastomosis procedure for a blocked coronary artery of a heart, the procedure comprising:

providing an incision in an intercostal space between two ribs of a patient, the incision providing access to a selected anastomosis site;

inserting into the incision a first blade to engage a first rib and a second blade to engage a second rib, and spreading apart the first and second blades to spread apart the first and second ribs;

lifting the second blade to offset the second blade and rib relative to the first blade and rib thereby exposing an internal mammary artery to direct visualization;

dissecting the internal mammary artery; and

performing the anastomosis.

9. The procedure of claim 8 wherein the patient is positioned on a surgical table, and wherein the second blade is lifted using a lifting mechanism that is mounted to the surgical table and extends upwardly to a position above the patient.

10. The procedure of claim 8 and further including:
 - reducing movement of the heart; and
 - suturing the internal mammary artery to an incision made in the blocked artery while the movement of the heart reduced.
11. A minimally invasive coronary anastomosis procedure for a blocked coronary artery of a heart, the procedure comprising:
 - providing an incision in an intercostal space between two juxtaposed ribs of a patient, the incision providing access to a selected anastomosis site on the blocked coronary artery;
 - inserting a spreader device between the two juxtaposed ribs such that when the spreader device is operated, the ribs are spread apart widening the incision;
 - dissecting an internal mammary artery;
 - reducing movement of the heart;
 - incising the blocked coronary artery downstream from the blockage; and
 - suturing the dissected internal mammary artery to the incision on the blocked coronary artery at the selected anastomosis site.
12. The procedure of claim 11 wherein the patient is positioned on a surgical table, and wherein the spreader device is lifted using a lifting mechanism that is mounted to the surgical table and extends upwardly to a position above the patient.
13. The procedure of claim 11 wherein the dissected internal mammary artery is sutured to the occluded coronary artery.

14. A device for use in a surgical procedure in which an incision is made between two juxtaposed ribs of a patient, the device comprising:

a first arm member having a proximal end portion and a distal end portion, the distal end portion having a rib engaging blade, and the distal and proximal end portions being hingedly attached to each other;

a second arm member having a proximal end portion and a distal end portion, the distal end portion having a rib engaging blade and the distal and proximal end portions being hingedly attached to each other;

a mechanism that operably connects the first and the second arm members at the proximal end such that the arm members are movable toward and away from each other; and

a rib offsetting device, the device being operably coupled to the blade of the second arm member, and adapted to move the blade portion of the second arm member in an upward direction thereby lifting the blade of the second arm member which results in lifting a section of the patient's ribs.

15. The device of claim 14 wherein the mechanism includes a rack bar fixedly attached to the first arm member at one end and at another end movably engages the proximal end portion of the second arm member such that the second arm member moves away and toward the first arm member along the rack bar.

16. The device of claim 14 wherein the first arm member further includes two hinge sections and a mid-section that is hingedly attached to the proximal end portion at one end and to the distal end portion at another end.

17. The device of claim 14 wherein the second arm member further includes two hinge sections and a mid-section that is hingedly attached to the proximal end portion at one end and to the distal end portion at another end.

18. The device of claim 14 wherein the distal end portion of the first arm member further includes a plurality of fingers extending away from the blade for retaining fatty tissue away from the incision.

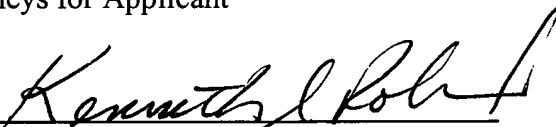
CONCLUSION

Applicants respectfully request a declaration of an interference with U.S. Pat. No. 5,882,299 to Hassan Rastegar et al. having the proposed Counts presented above.

Respectfully submitted

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Dated: January 24, 2000

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